

# Home-Based Functional Electrical Stimulation Cycling Enhances Quality of Life in Individuals with Spinal Cord Injury

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**Background:** With advances in medicine and increased survival rates, the focus of health care after spinal cord injury (SCI) has evolved from extending life to increasing independence and quality of life (QOL). Because enhancing QOL is an ultimate goal of the rehabilitation process, research involving the improvement of QOL is of great importance. **Objective:** The purpose of this study was to determine the effects of a home-based functional electrical stimulation lower extremity cycling (FES-LEC) program on the QOL of persons with SCI. **Design:** Eleven veterans with posttraumatic C4-T11 AIS A-C SCI participated in 8 weeks of 3 times weekly home-based FES-LEC. QOL was assessed using the World Health Organization Quality of Life (WHOQOL-BREF) questionnaire. Tests were completed by all participants prior to and after the 8-week FES-LEC program. **Results:** There were significant increases in the physical and environmental domain QOL scores. There were nominal nonsignificant increases in the psychological and social domain QOL scores. **Conclusions:** The results of this study provide evidence that home-based FES-LEC 3 times per week for 8 weeks has the potential to result in QOL improvements. **Key words:** cycling, electrical stimulation quality of life, spinal cord injury

With medical advances over the past century, there has been a dramatic increase in life-span of those with spinal cord injury (SCI).<sup>1</sup> This has changed the focus of health care after SCI from extending life to increasing independence and quality of life (QOL).<sup>2</sup> Chappell and Wirz<sup>3</sup> state that enhancing QOL is the ultimate goal of rehabilitation, and the overall processes of optimizing physical function and independence comprise 2 of the many components of enhancing the QOL of persons with SCI. The US Surgeon General reports that physical activity is an important factor in promoting QOL. Persons with SCI have been shown to have decreased QOL after injury,<sup>4-6</sup> thus research measuring the effects of physical activity on the QOL of persons with SCI is necessary.

The World Health Organization (WHO) defines QOL as the individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. This concept takes into account the effect of physical health, psychological state, level of independence, social relationships, personal beliefs, and relationship to pertinent

environmental features.<sup>7</sup> One intervention that has been associated with the enhancement of QOL is physical activity.<sup>8</sup> White and colleagues<sup>9</sup> studied the effects of leisure time physical activities on community-dwelling older adults and found that physical activity and QOL were linked through self-efficacy, whereby physical activities that produce a positive experience and positive feedback are most likely to improve QOL. The study of the relationship between QOL and physical activity for persons with SCI is a more recent undertaking, thus there are relatively few studies that have targeted the psychological effects of regular physical activity in persons with SCI. Hicks et al<sup>2</sup> studied the effects of an upper body resistance training program using arm ergometry twice weekly for 9 months on the QOL of 34 individuals with SCI. Results showed positive QOL factors; the exercise group reported significantly less stress, fewer depression symptoms, and greater satisfaction with their physical functioning. The results also showed a

**Table 1.** Physical characteristics of subjects

Subject	Age, years	Weight, kg	Height, cm	LOI	AISa	TSI, years	Sex
1	64	74.62	170.18	C5	B	1.0	M
2	31	68.04	175.26	T4	A	12	M
3	31	88.09	185.42	C7	B	0.5	M
4	22	58.2	182.88	C6	C	0.5	M
5	31	73.94	172.72	C7	A	4.0	M
6	52	63.14	172.72	C4	B	33	M
7	37	68.17	182.37	C6	B	12	M
8	50	126.10	182.88	C5	B	3.0	M
9	59	104.78	167.64	T7	C	0.7	M
10	38	73.94	185.42	C6	C	19	M
11	27	100.02	175.26	C5	B	1.0	M

Note: AIS = American Spinal Injury Association Impairment Scale; LOI = level of injury; M = male; TSI = time since injury.

<sup>a</sup>AIS A = no motor or sensation below injury; AIS B = no motor but some sensation below the level of injury; AIS C = some motor and some sensation below the level of injury.

nonsignificant increase in satisfaction in the self-perceived physical appearance of the exercise group relative to the control group. Fitzwater,<sup>10</sup> a general medical practitioner and FES researcher, provided a personal view as a self-exerciser reporting the perception of improved body image and a preference for functional electrical stimulation lower extremity cycling (FES-LEC) over hand and arm activities.

Our group has recently reported case reports utilizing a home-based FES-LEC program. Two older male adults with motor complete tetraplegia participated in FES-LEC 3 times per week for 9 weeks and 6 months, respectively. The results in both case reports showed improvements in perceived body image and self-esteem.<sup>11,12</sup> However, information concerning the effects of exercise, particularly FES-LEC on QOL of those with SCI, remains limited. The purpose of this study was to determine the effects of an Internet-connected home-based FES cycling program on the QOL (physical, psychological, social, and environmental health) of persons with SCI.

## Methods

### Subjects

Eleven male veterans with posttraumatic C4-T11 American Spinal Injury Association Impairment Scale (AIS) A-C SCI participated in the current

study. The AIS scores were obtained from medical records and were not used as a variable being tested in this study. The veterans were nonambulatory, wheelchair reliant, and at least 6 months post injury. Inclusion criteria included being a veteran with SCI, 18 to 70 years old, and with the capacity to respond with muscular contractions to electrical stimulation of paralyzed muscles. Exclusion criteria included uncontrolled hypertension, uncontrolled coronary artery disease, uncontrolled autonomic dysreflexia, uncontrolled pain, fragility bone fracture, pressure ulcers greater than grade 2, deep venous thrombosis within the past 3 months, pregnancy, and any physical limitation that would preclude the ability to perform the FES-LEC activity. The participants were recruited from veterans attending physical therapy at our medical center. All physical therapy sessions were completed prior to starting this study. The mean (SD) age was 40.18 (13.89) years with an age range from 22 to 64 years. The mean (SD) average time since injury (TSI) was 7.88 (10.40) years with a range from 0.5 to 33 years (**Table 1**). Of the participants, 64% were younger than 50 years, 73% had a self-professed history of regular physical activity, 73% had tetraplegia, 18% had a history of depression, and 82% had reports of recurrent pain that did not involve the exercise program. Furthermore, 45% had a TSI of less than 3 years, 19% had 3 to 10 years, and 36% had more than 10 years.

All participants reviewed and signed a written VA Human Subjects Research Consent form. This study was approved by the institutional review board of the McGuire VA Medical Center, and all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed. Research was conducted in accordance with the Declaration of the World Medical Association.

### FES-LEC training

All participants were screened and cleared for participation by their physician prior to starting the home-based FES-LEC program. The participants also underwent a trial FES-LEC session in the McGuire VA Medical Center SCI exercise laboratory so that heart rate, blood pressure, and possible autonomic dysreflexia symptoms could be monitored. After successful completion of the laboratory trial, they were cleared to begin home-based FES-LEC.

During this study, an RT300 FES-LE cycle (Restorative Therapies Inc., Baltimore, MD) was placed in each participant's home. The RT300 FES-LE cycle electrically stimulated the quadriceps, hamstrings, and gluteal muscles through wires that were connected to surface electrodes. The Internet connectivity of the RT300 allowed clinicians to remotely make distant alterations to the exercise and cycle parameters. The cycling system stored performance data including time, distance, and power and the session parameters such as current amplitude, pulse width, current frequency, cycling speed, and resistance. The Internet connectivity allowed for the safe optimization of training. The RT300 FES-LE cycle also eliminated the need for the participants to transfer from their chair to the cycle, as the participants cycled from their own wheelchairs.

All participants were asked to cycle 3 times per week with at least 1 day of noncycling between sessions. Petrofsky et al<sup>13</sup> found that this frequency protocol was more effective for increasing strength and endurance with electrical stimulation than 5 days per week or 1 day per week. Exercise sessions were monitored by the research staff via Internet

connection. Cycle parameters were individualized depending on the comfort of the participants and the amount of current needed to perform the cycling activity. The cycling parameters were similar to those used in other FES-LEC studies.<sup>14</sup> The electrical parameters ranged from 70 to 140 mA for current amplitude, 250 to 400  $\mu$ s for pulse width, and 33 to 50 Hz for frequency. Speed was advanced between 30 and 50 rpm as tolerated with an initial resistance of 0.5 Nm. The RT300 cycling system allowed the resistance to be set on automatic so that the RT300 cycle adjusted the resistance to allow the set speed. Patient comfort, preference, and safety were taken into account when selecting the cycling speed, and a maximal speed of 50 rpm was set because speeds above 50 rpm tended to cause excessive trunk movement. We wanted to avoid undue stress to the hip and knee joints, which we feared might be created with the excessive trunk movement. Initial cycling duration was based on the participants' ability to perform the cycling activity using the electrical current as the stimulus to elicit muscle contractions, and cycling duration was increased over the 8-week period as the participants tolerated until a goal of between 40 and 60 minutes of continuous active FES cycling was achieved. The 8-week time period was selected based on convenience and because we believed, based on previous experience, that the 8-week timeframe was adequate to produce a difference in QOL.<sup>11</sup> Participants and participant helpers were provided training concerning the placement of electrodes and the FES-LEC system.

Latex-free adhesive electrodes (7.5 x 10 cm) were placed on the skin of the legs and on the buttocks (6 x 9 cm). The electrodes were placed as follows: For the quadriceps, one electrode was placed on the skin 2 to 3 cm above the superior aspect of the patella over the vastus medialis muscle, and the other was placed lateral to and 30 cm above the patella over the vastus lateralis muscle. For the hamstrings, one electrode was placed 2 to 3 cm above the popliteal fossa, and the other electrode was placed 30 cm above the popliteal fossa. For the gluteus maximus, 2 electrodes were placed parallel and on the bulk of the muscle belly of each buttock with 3 to 4 cm between electrodes.

**Table 2.** WHOQOL-BREF domains

Domains	QOL features
Domain 1. Physical	Pain and discomfort Energy and fatigue Physical health Sleep and rest Dependence on medications/medical aids Work capacity Mobility
Domain 2. Psychological	Positive feelings Learning and concentration Self-esteem Body image and appearance Negative feelings Spirituality and personal beliefs
Domain 3. Social	Personal relationships Social support Sexual activity
Domain 4. Environment	Freedom and physical safety Home environment Financial resources Accessibility to health and social care Transportation

Adapted from World Health Organization Quality of Life (WHOQOL-BREF) questionnaire. [http://www.who.int/mental\\_health/media/en/76.pdf](http://www.who.int/mental_health/media/en/76.pdf)

### Quality of life questionnaire

The WHOQOL-BREF questionnaire was designed to measure the impact that disease and health intervention have on QOL. The 26-item questionnaire categorizes QOL into 4 dimensions: physical, psychological, social, and environmental health (Table 2). Each item is rated on a 5-point scale. This questionnaire has been validated and is reported to be the most acceptable and established instrument to assess QOL after SCI.<sup>13</sup> The questionnaire was completed by all participants before and after the 8-week exercise program.

### Analysis

Linear mixed-effects models were used to model the QOL scores (physical, psychological, social, and environmental) before and after the exercise program. This model was chosen because the outcome variables were normally distributed; there were repeated measures, because each

participant was measured before and after the 8-week exercise program. All models assumed an unstructured variance covariance structure for the repeated measures within a participant. The level of significance was placed at  $P = .05$ .

## Results

### QOL domain scores

There were significant increases in physical ( $F_{1,10} = 13.2, P = .01$ ) and environmental ( $F_{1,10} = 6.59, P = .03$ ) QOL scores from pre-exercise testing to postexercise testing. Physical QOL scores increased by 2.30 units and the environmental QOL scores increased by 1.89 units from pre to post test. There were nominal nonsignificant increases in psychological ( $F_{1,10} = 2.95, P = .12$ ) and social ( $F_{1,10} = 2.17, P = .17$ ) QOL scores. The psychological QOL scores nominally increased by 1.02 units and the social QOL scores nominally increased by 1.27 units.

## Discussion

There was an increase in all 4 QOL domain scores (physical, psychological, social, and environmental) with the physical and environmental domains sustaining a statistically significant increase while the psychological and social domains underwent nonstatistically significant nominal increases. Increased physical domain scores represent enhanced perception of physical health, work capacity, and comfort. The authors theorize that with the ability to perform greater amounts of cycling regarding time and distance, participants may have perceived increased physical capacity that may translate into feelings of increased health. The environmental domain involves perception of physical safety and feelings of freedom and comfort in the home. Along with a realization of enhanced physical capacity, there may have been an increased perception of personal security through an awareness of improved physical fitness. The authors theorize that this may also translate into decreased apprehension concerning accessibility of health care and ability to travel.

Although the psychological domain did not show a statistically significant increase, the nominal

gain is not surprising because perceptions of increased physical health and capacity are often linked to positive feelings related to self-esteem.<sup>14</sup> The authors theorize that the appearance of muscular contractions with FES-LEC in muscles that had been chronically nonfunctioning due to paralysis may also have translated into perceptions of enhanced body image. Likewise, the enhanced perception of the ability to perform work and increased self-esteem could possibly have impacted personal involvement in relationships, which may explain the nominal increase in the social domain. Although until recent years the effects of physical activity on the QOL of individuals with SCI has gone largely unstudied, Stevens and colleagues<sup>6</sup> reported a strong positive association between physical activity and the QOL among 62 males and females with SCI after matching scores from QOL and physical activity level questionnaires. Hicks and associates<sup>2</sup> found enhanced self-concept and QOL in persons with SCI after structured volitional exercise 2 times per week for 9 months. The results of our study support the findings of Hicks et al and Stevens et al. The results of the current study also support our previous findings in 2 case reports of individuals with chronic tetraplegia. One participant improved in the psychological domain after FES-LEC 3 times per week of 9 weeks and the other improved in the physical and psychological domains after 6 months or FES-LEC 3 times per week.<sup>11,12</sup> The physical and psychological domains of the WHOQOL-BREF questionnaire reflect comfort or pain level, energy level, and restfulness and positive feelings, self-esteem, body image and appearance, and concentration, respectively (**Table 2**). The results of the current study also support research concerning the enhancing effects of physical activity on the QOL and sense of well-being in persons who are not spinal cord injured.<sup>15</sup>

### Limitations

Because of the complexities involved with SCI, it is often difficult to recruit large numbers of participants for research studies. As such, the small number of participants (11) in this study is a limitation. Factors concerning age, history of exercise, level of injury (LOI), TSI, history of depression, and pain may impact QOL and thus also impact the level of effect that FES-LEC has on QOL. However, because of the small number of participants in this study, conclusions from information concerning these factors cannot be drawn but will rather be used as pilot work for a larger study. Along with a limited number of participants, the lack of female participants disallows comparisons by gender. Although the WHOQOL-BREF is commonly used and well validated, QOL is a subjective concept and is vulnerable to psychological variations as impacted by life events.

### Conclusions

The results of this study provide evidence that home-based FES-LEC 3 times per week for 8 weeks can result in QOL improvements. Factors concerning age, history of exercise, LOI, TSI, history of depression, and pain unassociated with the FES-LEC activity were examined; however, because of the small number of participants, division into smaller subgroups makes it difficult to draw conclusions concerning their effects on the ability of FES-LEC to impact QOL. Further study with a larger number of participants is needed to corroborate the results of this study.

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The authors declare no conflict of interest.

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